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09/927,424	08/09/2001	Edward Shipwash	21059-000110	6393

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EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/14/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/927,424

Applicant(s)

SHIPWASH, EDWARD

Examiner

Shar Hashemi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11/25/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 61-92 and 97-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-60 and 93-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. The applicant's election of claims 1-60 and 93-96 without traverse was made in Paper No. 9. Claims 61-92 & 97-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-60 and 93-96 are currently under examination.

### *Oath/Declaration*

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth in this communication. The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" (PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or

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oath) should indicate the following in the upper right hand corner: Issue Batch Number, date of the "Notice of Allowance" (PTOL-85), and application number.

### ***Drawings***

3. The drawings are objected to because the description of on page 12, par. 69 does not have a corresponding Figure 24. Each drawing description must have a corresponding figure. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the abandonment of the application.

### ***Specification***

4. The use of the trademarks "Texas Red" (page 34, line 28) has been noted in this application. All trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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5. The disclosure should be examined for spelling errors: At page 13, line 10, delete "tthree" and insert "three". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3, 22, 25, 51, 57, and 95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The abbreviation "PP<sub>i</sub>" renders claims 2 and 57 indefinite. It is unclear as to whether the abbreviation "PP<sub>i</sub>" refers to inorganic pyrophosphate or proton pump inhibitor. Amending the claim to incorporate the definition of the abbreviation "PP<sub>i</sub>" would obviate the rejection.

B) The acronym "AA-AMP" renders claims 3, 25 and 57 indefinite. It is unclear as to whether the acronym "AA-AMP" refers to aminoacyl adenosine-monophosphate complex or another complex. Amending the claims to incorporate a definition of the acronym "AA-AMP" would obviate the rejection.

C) Claim 22 recites the limitation "said second product" in page 122, line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites a method whereby a first product is formed and detected. It is unclear as to whether "said second product" refers to the first product or another materially different product. Amending the claims to clarify the antecedent basis would obviate the rejection.

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D) Claim 51 recites the limitation "said ternary complex" in page 125, line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 3 recites detecting an aminoacyltRNA synthetase:AA-AMP complex. It is unclear as to whether "said ternary complex" refers to the aminoacyltRNA synthetase:AA-AMP complex or another materially different ternary complex. Amending the claims to clarify the antecedent basis would obviate the rejection.

E) Claim 95 contains the trademark/trade name "Texas Red". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe fluorescent labels and, accordingly, the identification/description is indefinite.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-38, 40-60, 93 and 96 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Shipwash in "Microarrays for Amino Acid Analysis and Protein Sequencing" August 10, 1999, Vol. 1, NanoNano Technology, Pages 1-21.

Shipwash teaches a method for detecting in a sample a primary amino acid comprising:

- A) contacting said sample with an aminoacyl tRNA synthetase of said amino acid to form a first product (see whole document, especially page 1 par. 1-3)
- B) detecting said first product (page 1, par. 1-3)
- C) contacting said first product with a tRNA for said primary amino acid to form a second product (page 12 par. 3 to page 15 par. 1)
- D) detecting said second product (page 12 par. 3 to page 15 par. 1)

In the detecting step, he teaches detecting  $PP_i$  and aminoacyl tRNA synthetase: AA-AMP complex of said primary amino acid (page 2 par. 4 to page 3 par. 3). He states said aminoacyl tRNA synthetase is immobilized on a solid support (page 5, see description A-B). He notes that the biological sample is a serum sample (page 9, par. 1). He mentions each of the 20 primary amino acids can be detected, wherein said sample comprises a plurality of primary amino acids including phenylalanine, glycine, and aspartic acid (page 1, par. 1-3). The author discloses that a sample is generated by N-terminal or C-terminal digestion of a polypeptide or protein (page 1, par. 1). Furthermore, he discloses said first product is labeled, where said first product is directly or indirectly detected (page 5 par. 2 to page 6 par. 1). In the contacting step, he reveals contacting said plurality of primary amino acids with a plurality of aminoacyl tRNA synthetases for the primary amino acid, wherein said contacting is with an aminoacyl tRNA

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synthetase for each primary amino acid, wherein plurality of amino acyl tRNA synthetases are spatially resolved and immobilized on a solid support (page 5, par. 1 to page 8 par. 3). He also teaches said plurality of aminoacyl tRNA synthetases are each located at a known locus of a spatial array, wherein said detecting is according to known locus (page 8, par 4 to page 9 par. 2). He mentions an array is formed by separately locating said aminoacyl tRNA synthetases each at a known locus of a microwell solid support (page 5, par. 1-3).

Shipwash teaches the second product is formed when said first product contacts said spatially separated tRNAs to form a second product (page 5 par. 3 to page 9 par. 1). He discloses the second product is aminoacyl tRNA or AMP (page 2 par. 4 to page 5 par. 6). In the second detecting step, he states identifying the detected amino acid according to said known location of said second product (page 5, par. 1 to page 8 par. 3). He notes said tRNA is immobilized on a solid support and said second product is immobilized on said solid support (page 5, par. 1 to page 8 par. 3). He reveals said tRNA for said primary amino acid is fluorescently labeled and said label is used to detect said second product (page 5, par. 1-6). In the second contacting step, he declares: contacting said aminoacyl tRNA with an elongation factor to form a ternary complex and detecting said ternary complex, wherein said elongation factor is labeled and immobilized on said amino acid biosensor (page 3, par. 1-3), wherein contacting said ternary complex with a biorecognition element and detecting the interaction of said ternary complex with said biorecognition element, wherein detecting of said ternary complex is by means of fluorescence detector or a surface plasmon resonance system (page 8, par. 3-4), wherein each of said tRNA for a primary amino acid comprises a unique label for detection, wherein said biorecognition element is bound to a transducer to create an amino acid biosensor (page 10, par.



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2-3). He states said factor is elongation factor Tu or elongation factor 1A in a complex with GTP analog (page 2, par. 1-3). He illustrates said GTP analog is a nonhydrolyzable analog of GTP which is incorporated into said ternary complex (page 3, par. 1-3). He describes said tRNA is fluorescently labeled and said label is used to detect the second product (page 5, par. 1-5). He also teaches said elongation factor is labeled (page 5, par. 1-6). He discloses said detecting is by means of a charged coupled device camera (page 8, par. 2-4).

He emphasizes the biorecognition element is a ternary complex probe immobilized on a transducer, where the transducer is an optical fiber (page 10, par. 2-3). He describes said tRNA for said primary amino acid is labeled with a fluorophore detectable tag. He notes the elongation factor is also labeled with a detectable tag (page 5, par. 3-6).

He teaches utilizing ternary complex probes to detect said ternary complex, where said ternary complex probe is an antibody or a nucleic acid (page 5, par. 4-6). He discloses said tRNA is labeled with a fluorophore and detected by fluorescence (page 5 par. 5 to page 6 par. 1).

He reveals a spatial array for the detection of a primary amino acid in a sample comprising:

- A) spatially separated aminoacyl tRNA synthetases or spatially separated tRNAs for a plurality of the primary amino acids each at a known locus on said array (see whole document, especially page 8 par. 1-4)
- B) means for contacting said sample with said spatially separated synthetases to form a first product (page 8, par 3-4).

He teaches said first product is aminoacyl tRNA synthetase:AA-AMP of said primary amino acid, , where said spatially separated aminoacyl tRNA synthetases collectively provide

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tRNA for each of the primary amino acids, where the said spatially separated aminoacyl tRNA synthetases are immobilized at a known locus and said spatially separated aminoacyl tRNAs are labeled (page 8, par. 1-4). He mentions biorecognition elements are arrayed on a film (page 10 par. 1 to page 11 par. 3). He teaches employing distinguishable fluorescent labels, wherein said elongation factor is labeled with one detectable label and said tRNA for said primary amino acid is labeled with a second detectable label (page 5 par. 3-6). He notes utilizing confocal laser scanners as a detection system (page 8, par. 3-4). He states contacting aminoacyl tRNA with an aptamer to form a ternary complex and detecting said ternary complex (page 5, par. 1-6).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash in "Microarrays for Amino Acid Analysis and Protein Sequencing" August 10, 1999, Vol. 1, NanoNano Technology, Pages 1-21 in view of VWR International "Molecular size exclusion chromatography", 2000, pages 1-2.

The teachings and suggestions of Shipwash have been previously discussed.

Shipwash does not teach a molecular sieve.

VWR teaches a molecular sieve whereby compounds of greater than about 6 kDa cannot pass and a method for performing molecular size exclusion chromatography (see whole document, especially page 1).

One of ordinary skill at the time the invention was made would have been motivated to apply VWR's molecular sieve to Shipwash' spatial array and method for detecting a primary amino acid using aminoacyl tRNA synthetase in order to utilize the molecular sieve to separate out the aminoacyl tRNA synthetase from the sample according to size (page 1). It would have been prima facie obvious to apply VWR's molecular sieve to Shipwash' spatial array and method for detecting a primary amino acid using aminoacyl tRNA synthetase in order to utilize the molecular sieve to separate out the aminoacyl tRNA synthetase from the sample according to size.

12. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash in "Microarrays for Amino Acid Analysis and Protein Sequencing" August 10, 1999, Vol. 1, NanoNano Technology, Pages 1-21 in view of Demandolx, D "Guidelines for multifluorescence confocal imaging: acquisition, processing and display" 1997, Microscopy and Analysis, Vol. 48, pages 1-9.

The teachings and suggestions of Shipwash have been previously discussed.

Shipwash does not teach Texas Red labels and dual-channel laser scanning confocal microscope.

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Demandolx teaches Texas Red and fluorescein labels, where the ratio of bound fluorescein and Texas Red labels is determined using a dual-channel laser scanning confocal microscope as a detection system (see whole document, especially pages 2-4).

One of ordinary skill at the time the invention was made would have been motivated to apply Demandolx's dual-channel laser scanning confocal microscope to Shipwash' spatial array and method for detecting a primary amino acid using aminoacyl tRNA synthetase in order to produce multicolor analysis and display (page 5). It would have been prima facie obvious to apply Demandolx's dual-channel laser scanning confocal microscope to Shipwash' spatial array and method for detecting a primary amino acid using aminoacyl tRNA synthetase in order to produce multicolor analysis and display.

### SUMMARY

13. No claims allowed.

### CONCLUSION


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is [shar.hashemi@uspto.gov](mailto:shar.hashemi@uspto.gov). However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

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Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703) 305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

February 26, 2003

  
GARY BENZION, PH.D.  
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